K122827

510(k) Summary of Safety and Effectiveness

Date Prepared: **September 12, 2012**

DEC 14 2012

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
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Establishment Registration No. 2184009

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Trade Name: Affinity Fusion® Oxygenator with Integrated Arterial Filter and Balance® Biosurface

Common Name: Oxygenator

Classification Name: Cardiopulmonary bypass oxygenator

Classification: Class II, 21 CFR 870.4350

Product Code: DTZ

Name of Predicate Device: Affinity NT Oxygenator 511T (K973760)

Device Description:

The Affinity Fusion Hollow Fiber Oxygenator with Integrated Arterial Filter and Balance Biosurface is a single use, microporous, hollow fiber, gas exchange device with plasma-resistant fiber and integrated heat exchanger. The oxygenator is coated on its primary blood contacting surfaces with Balance Biosurface to reduce platelet activation and adhesion and preserve platelet function.

Intended Use:

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

Contraindications:

Do not use this device for any purpose other than indicated.

Comparison to the Predicate Device:

The Affinity Fusion Oxygenator Model BB811 has the same intended use and principles of operation and technology when compared to the predicate device. The design incorporated an integrated heat exchanger and an integrated arterial filter. The material used to manufacture the housing of the oxygenator is a copolyester material that is Bisphenol A-free (BPA free).

Intended Use:

The Affinity Fusion Oxygenator has the same intended use as the predicate Affinity NT oxygenator (K973760) with the addition of the filtering capability due to the integration of arterial filter within the fiber bundle assesmbly.

- **Design and Materials**:

  The design and the materials of the Affinity Fusion Oxygenator and the predicate device are essentially the same. The design of the oxygenator device is similar in that they each contain a heat exchanger for temperature control, and a fiber bundle assembly for gas transfer. The device is manufactured with various adhesives and urethanes. The housing of the Affinity Fusion oxygenator is made of a Bisphenol A-free (BPA-free) Eastman Tritan ^{TM} Copolyester, MX731, which differs from the polycarbonate material used in the predicate devices. The Affinity Fusion oxygenator Model BB811 is provided with Balance Biosurface coating. Balance is a biocompatible surface coating that increases the thromboresistance of the blood contact surfaces. Balance is a heparin free version of Trillium coating. Trillium coating is available on the Affinity NT Hollow Fiber Oxygenator.

- **Principles of Operation and Technology**:

  The principles of operation of the subject device and the predicate devices are essentially identical. Blood is pumped into the heat exchanger device whereby blood temperature is controlled with the use of essentially a water bath. After the blood exits the heat exchanger, it enters the oxygenator device through the fiber bundle assembly through which the gas transfer occurs (i.e., introduction of oxygen; removal of carbon dioxide). The transfer process occurs via diffusion across the walls of the hollow fiber membranes contained within the oxygenator.

- **Performance**:

  In vitro testing was carried out in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and

FDA Staff' issued on November 13, 2000, " ISO 7199 "Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)"; and ISO 15675 "Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters".

In vitro testing was carried out to demonstrate both the substantial equivalence with the predicate device and also to comply with safety and effectiveness requirements.

Testing supplied in the 510(k) premarket notification includes performance tests, physical and mechanical integrity tests that demonstrate compliance with performance specifications.

The tests that were performed are listed in the following summary table. The Affinity Fusion Oxygenator passed each test mentioned in the table below.

Test	Test Classification	Test Title
1.	Functional/Performance	Gas Transfer
2.	Functional/Performance	Heat Exchanger Performance
3.	Functional/Performance	High Flow Blood Trauma
4.	Functional/Performance	Min Flow Blood Trauma
5.	Functional/Performance	Time to Prime
6.	Functional/Performance	Gross Air Handling
7.	Functional/Performance	Filtration Efficiency
8.	Physical/Mechanical	Cap Pulls
9.	Physical/Mechanical	Integrity
10.	Physical/Mechanical	Port Break and Tube Pull
11.	Physical/Mechanical	Luer port design - sampling port
12.	Physical/Mechanical	Luer port design - air purge line
13.	Functional/Performance	Balance Coverage/Leaching
14.	Functional/Performance	Particulate Shedding

Conclusion:

The data included in this submission is sufficient to provide reasonable assurance of the safety and effectiveness of the device and the Affinity Fusion® Oxygenator with Integrated Arterial Filter is substantially equivalent to the legally marketed predicate device, Affinity NT Oxygenator 511T (K973760).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 14 2012

Medtronic Cardiovascular
Mary E. Donlin, Senior Regulatory Affairs Specialist
8200 Coral Street NE
Mailstop MVS83
Mounds View, MN 551112

Re: K122827
Trade/Device Name: Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: September 12, 2012
Received: September 18, 2012

Dear Ms. Donlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

4.0 Indications for Use Statement

510(k) Number (if known): K122827

Device Name:

Affinity Fusion® Oxygenator with Integrated Arterial Filter and Balance® Biosurface

Indications for Use:

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122827